Patent
Attorney's Docket No. 002010-593

#3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Jing Wu, et al.

Application No.: Unassigned

Filed: ON EVEN DATE HEREWITH

For: CYCLOALKYL, LACTAM, LACTONE AND RELATED COMPOUNDS, PHARMACEUTICAL COMPOSITIONS COMPRISING SAME, AND METHODS FOR INHIBITING β-AMYLOID PEPTIDE RELEASE AND/OR ITS SYNTHESIS BY USE OF SUCH COMPOUNDS

Group Art Unit: Unassigned

Examiner: Unassigned

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. §1.98, a copy of each of the following documents was submitted in Application No. 08/996,422, upon which is based a claim for priority under 35 U.S.C.§120:

1. U.S. Patent No. 3,657,341, issued April 18, 1972, to Thorne.
2. U.S. Patent No. 4,477,464, issued October 16, 1984, Slade, et al.
3. U.S. Patent No. 4,666,829, issued May 19, 1987, to Glenner, et al.
4. U.S. Patent No. 4,977,168, issued December 11, 1990, to Bernat, et al.
5. U.S. Patent No. 5,238,932, issued August 24, 1993, to Flynn, et al.
6. U.S. Patent No. 5,283,241, issued February 1, 1994, to Bochis, et al.
7. U.S. Patent No. 5,284,841, issued February 8, 1994, to Chu, et al.
8. U.S. Patent No. 5,324,726, issued June 28, 1994, to Bock, et al.
9. U.S. Patent No. 5,360,802, issued November 1, 1994, to Chambers, et al.

10. U.S. Patent No. 5,420,271, issued May 30, 1995, to Warchawsky, et al.
11. U.S. Patent No. 5,556,969, issued September 17, 1996, to Chambers, et al.
12. U.S. Patent No. 5,633,251, issued May 27, 1997, to Claremon, et al.
13. U.S. Patent No. 5,658,901, issued August 19, 1997, to Claremon, et al.
14. U.S. Patent No. 5,712,397, issued January 27, 1998, to Esser, et al.
15. U.S. Patent No. 5,770,573, issued June 23, 1998, to Arrhenius, et al.
16. Canadian Patent No. 1 063 108, published September 25, 1979.
17. European Patent No. 0 167 919, published January 15, 1986.
18. European Patent No. 0 284 256, published September 28, 1988.
19. European Patent No. 0 349 949, published January 10, 1990.
20. European Patent No. 0 376 849, published July 4, 1990. (Abstract in English)
21. European Patent No. 0 434 360, published June 26, 1991.
22. European Patent No. 0 434 364, published June 26, 1991.
23. European Patent No. 0 434 369, published June 26, 1991.
24. European Patent No. 0 490 590, published June 17, 1992.
25. European Patent No. 0 514 133, published November 19, 1992.
26. European Patent No. 0 523 845, published January 20, 1993.
27. European Patent No. 0 549 039, published June 30, 1993.
28. European Patent No. 0 647 632, published April 12, 1995.
29. European Patent No. 0 652 009 A1, published June 10, 1995.
30. European Patent No. 0 667 344, published August 16, 1995.
31. European Patent No. 0 677 517 A1, published October 18, 1995.
32. European Patent No. 0 732 399 A, published September 18, 1996.
33. European Patent No. 0 778 266 A1, published November 6, 1997.
34. GB 1 519 495, published July 6, 1978.
35. GB 1 573 931, published August 18, 1980.
36. GB 2 272 439, published May 18, 1994.
37. GB 2 290 788 A, published January 10, 1996.
38. JP 04210967 A2, published August 3, 1994.
39. JP 06145148 A2, published May 24, 1994.

40. JP 07304770 A2, published November 21, 1995.
41. JP 10072444 A2, published March 17, 1998.
42. International Publication No. WO 92/01683, published February 6, 1992.
43. International Publication No. WO 92/16524, published October 1, 1992.
44. International Publication No. WO 93/19052, published September 30, 1993.
45. International Publication No. WO 93/19063, published September 30, 1993.
46. International Publication No. WO 94/05693, published March 17, 1994.
47. International Publication No. WO 94/04531, published March 3, 1994.
48. International Publication No. WO 94/07486, published April 14, 1994.
49. International Publication No. WO 94/10569, published May 11, 1994.
50. International Publication No. WO 95/03289, published February 2, 1995.
51. International Publication No. WO 95/03290, published February 2, 1995.
52. International Publication No. WO 95/09838, published April 13, 1995.
53. International Publication No. WO 95/14671, published June 1, 1995.
54. International Publication No. WO 95/21840, published August 17, 1995
55. International Publication No. WO 95/23810, published September 8, 1995.
56. International Publication No. WO 95/25118, published September 21, 1995.
57. International Publication No. WO 95/32191, published November 30, 1995.
58. International Publication No. WO 96/05839, published February 29, 1996.
59. International Publication No. WO 96/16981, published June 6, 1996.
60. International Publication No. WO 96/19492, published June 27, 1996.
61. International Publication No. WO 96/20725, published July 11, 1996.
62. International Publication No. WO 96/22966, published August 1, 1996.
63. International Publication No. WO 96/40146, published December 19, 1996.
64. International Publication No. WO 96/40653, published December 19, 1996.
65. International Publication No. WO 96/40654, published December 19, 1996.
66. International Publication No. WO 96/40655, published December 19, 1996.
67. International Publication No. WO 96/40656, published December 19, 1996.
68. International Publication No. WO 97/30072, published August 21, 1997.
69. International Publication No. WO 97/38705, published October 23, 1997.

70. International Publication No. WO 98/00405, published January 8, 1998.

71. International Publication No. WO 98/25930, published June 18, 1998.

72. International Publication No. WO 98/28268, published July 2, 1998.

73. International Publication No. WO 98/38177, published September 3, 1998.

74. Aquino, et al. "Discovery of 1,5-Benzodiazepines with Peripheral Cholecystokinin (CCK-A) Receptor Agonist Activity. 1. Optimization of the Agonist "Trigger." *J. Med. Chem.* 39: 562-569 (1996).

75. Arienti, et al. "Regioselective Electrophilic Alkylation of Anilines with Phanylacetrylene in the Presence of Montmorillonite KSF." *Tetrahedron* 53(10): 3795-3804 (1997).

76. Bock, et al. "Synthesis and Resolution of 3-Amino-1,3-dihydro-5-phenyl-2H-1,4-benzodiazepin-2-ones." *J. Org. Chem.* 52: 3232-3239 (1987).

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78. Bock, et al. "Selective Non-Peptide Ligands for an Accommodating Peptide Receptor. Imidazobenzodiazepines as Potent Cholecystokinin Type B Receptor Antagonists." *Bioorg. and Med. Chem. Lets.* 2(9):987-998 (1994).

79. Brown, et al. "A Revision of the structureof "7-Phenyloxindole"; Photochemical Synthesis and Pyrolytic Behaviour of Authentic 7-Phenyloxindole." *Tet. Lets.* 8: 667-670 (1971).

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81. Cordell. "B-Amyloid Formation as a Potential Therapeutic Target for Alzheimer's Disease." *Ann. Rev. Pharmacol. Toxicol.* 34:69-89 (1994).

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85. Finizia, et al. "Synthesis and Evaluation of Novel 1,5-Benzodiazepines as potent and selective CCK-B Ligands, Effect of the Substitution of the N-5 Phenyl with Alkyl Groups." *Bioorg. & Medicinal Chemistry Letters.* 6(24):2957-2962 (1996).

86. Hirst, et al. "Discovery of 1,5-Benzodiazepines with Peripheral Cholecystokinin (CCK-A) Receptor Agonists Activity (II): Optimization of the C3 Amino Substituent." *J. Med. Chem.* 39: 5236-5245 (1996).

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89. Lowe, et al. "A Water Soluble Benzazepine Cholecystokinin-B-Receptor Antagonist." *Bioorg. and Med. Chem. Lets.* 5(17): 1933-1936 (1995).

90. Lowe, et al. "5-Phenyl-3-ureidobenzzazepin-2-ones as Cholecystokinin-B Receptor Antagonists." *J. Med. Chem.* 37: 3789-3811 (1994).

91. Milligan, eet al. "Intramolecular Schmidt Reactions of Alkyl Azides with Ketones: Scope and Stereochemical Studies." *J. Am. Chem. Soc.* 117: 10449-10459 (1995).

92. Papadopoulos, et al. Anodic Oxidation of N-Acyl and N-Alkoxylcarbonyl Dipeptide Esters as a Key Steop for the Formation of Chiral Heterocyclic Synthetic Building Blocks." *Tetrahedron* 47(4/5):563-572 (1991).

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94. Reiter, et al. "Crystallization-Induced Asymmetric Transformation: Stereospecific Synthesis of a Potent Peripheral CCK Antagonist." *J. Org. Chem.* 52: 955-957 (1987).

95. Rittle, et al. "A New Amine Resolution Method and its Application to 3-Aminobenzodiazepines." *Tet. Lets.* 28(5):521-522 (1987).

96. Robl. "Synthesis of 2-(4-Fluorophenyl)-4-isopropyl-3-quinolinecarbaldehyde: A New Route to 2,3,4-Substituted Quinolines." *Synthesis*. 56-58 (1991).

97. Satoh, et al. "New 1,4-Benzodiazepine-2-one Derivatives as Gastrin/ Cholecystokinin-B Antagonists." *Chem. Pharm. Bull.* 43(12): 2159-2167 (1995).

98. Satyanarayana, et al. "Carbonylation of Benzyl Halides Using CoCl2/NaBH4/ CO/NaOH Reagent System." *Tet. Lets*. 28(23): 2633-2636 (1987).

99. Semple, et al. "Design, Synthesis, and Evolution of a Novel, Selective, and Orally Bioavailable Class of Thrombin Inhibitors: P1-Argininal Derivatives Incorporating P3-P4 Lactam Sulfoamide Moieties." *J. Med. Chem.* 39: 4531-4536 (1996).

100. Sherrill, et al. "An Improved Synthesis and Resolution of 3-Amino-1,3 dihydro-5-phenyl-2H-1,4-benzodiazepinn-2-ones." *J. Org. Chem.* 60:730-734 (1995).

101. Showell, et al. "High Affinity and Potent, Water-Soluble 5-Amino-1,4-Benzodiazepine CCKB/Gastrin Receptor Antagonists Containing a Cationic Solubilizing Group." *J. Med. Chem.* 37:719-721 (1994).

102. Smith, et al. "β-APP Processing as a Therapeutic Target for Alzheimer's Disease." *Current Pharmaceutical Design*. 3:439-445 (1997).

103. Stewart. "Syntheses of L-Kynurenine Peptides Conducted Without Masking the Side-Chain Amino Group." *Aust. J. Chem.* 33: 633-640 (1980).

104. Van Niel, et al. "CCKB Selective Receptor Ligands: Novel 1,3,5-Trisubstituted Benzazepin-2-ones." *Bioorganic & Medicinal Chemistry Letters*. 5(13):1421-1426 (1995).

105. Varnavas, et al. "Synthesis of New Benzodiazepine Derivatives as Potential Cholecystokinin Antagonists." *Il Farmaco*. 46(2):391-401 (1991).

106. Waldmann, et al. "Selective Enzymatic Removal of Protecting Groups: The Phenylacetamide as Amino Protecting Group in Phosphopeptide Synthesis." *Tet. Lets*. 37(48): 8725-8728 (1996).

107. Warshawsky, et al. "The Synthesis of Aminobenzazepinones as Anti-Phenylalanine Dipeptide Mimics and Their Use in NEP Inhibition." *Bioorg. & Med. Chem. Lets*. 6(8): 957-962 (1996).

108. Zoller, et al. "Aminoalkylation of Cercaptans with Glyoxylic Acid Derivatives." *Tetrahedron*. 31: 863-866 (1973).

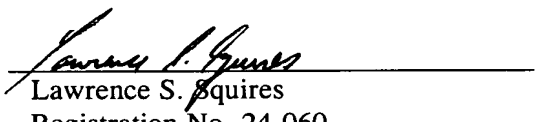
The documents are being submitted before the first Office Action on the merits, therefore no fee or certification is required under 37 C.F.R. § 1.97(b). In the event that an Office Action is mailed prior to receipt of this paper, the Commissioner is hereby authorized to charge the requisite fees under 37 C.F.R. § 1.97(c) for submission of this paper to Deposit Account No. 02-4800.

By citing the above references, Applicants do not acquiesce or admit that any of these documents are "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
Lawrence S. Squires
Registration No. 24,060

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650)622-2300

Date: July 26, 2001

Patent
Attorney's Docket No. 002010-593

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR FILING CONTINUATION/DIVISIONAL APPLICATION UNDER 37 C.F.R. § 1.53(b)

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is a request for filing a [ ] continuation [X] divisional application under 37 C.F.R. § 1.53(b) of pending Application No. 08/996,422 filed on December 22, 1997, for CYCLOALKYL, LACTAM, LACTONE AND RELATED COMPOUNDS, PHARMACEUTICAL COMPOSITIONS COMPRISING SAME, AND METHODS FOR INHIBITING β-AMYLOID PEPTIDE RELEASE AND/OR ITS SYNTHESIS BY USE OF SUCH COMPOUNDS, by the following named inventor(s):

(a)	Full Name	Jing Wu
(b)	Full Name	Jay S. Tung
(c)	Full Name	Eugene D. Thorsett
(d)	Full Name	Michael A. Pleiss
(e)	Full Name	Jeffrey S. Nissen
(f)	Full Name	Jeffrey Neitz
(g)	Full Name	Lee H. Latimer
(h)	Full Name	Varghese John
(i)	Full Name	Stephen Freedman
(j)	Full Name	Thomas C. Britton
(k)	Full Name	James E. Audia
(l)	Full Name	Jon K. Reel
(m)	Full Name	Thomas E. Mabry
(n)	Full Name	Bruce A. Dressman
(o)	Full Name	Cynthia L. Cwi
(p)	Full Name	James J. Droste
(q)	Full Name	Steven S. Henry
(r)	Full Name	Stacey L. McDaniel
(s)	Full Name	William Leonard Scott
(t)	Full Name	Russell D. Stucky
(u)	Full Name	Warren J. Porter

[ ] Applicant(s) hereby requests that the above-captioned application **NOT BE PUBLISHED** under 35 U.S.C. § 122(b) and 37 C.F.R. § 1.211. The undersigned hereby certifies that the invention disclosed in this application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

[X] The entire disclosure of the prior application from which a copy of the oath or declaration is supplied herewith is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

[ ] This application is being filed by less than all the inventors named in the prior application. In accordance with 37 C.F.R. 1.63(d)(2), the Commissioner is requested to delete the name(s) of the following person or persons who are not inventors of the invention being claimed in this application.

(a) Full Name _____

(b) Full Name _____

(c) Full Name _____

[ ] This application is being filed by more than all the inventors named in the prior application. In accordance with 37 C.F.R. 1.63(d)(5), a new oath or declaration is enclosed, and the Commissioner is requested to add the name(s) of the following person or persons who are inventors of the invention being claimed in this application.

(a) Full Name _____

(b) Full Name _____

(c) Full Name _____

[ ] Applicant(s) suggests Figure _ for inclusion on the front page of the patent application publication and/or patent.

1. [X] Enclosed is a copy of the prior Application No. 08/996,422 as originally filed on December 22, 1997, including copies of the specification, claims, drawings and the executed oath or declaration as filed.

2. [ ] Enclosed is a revised prior application and a copy of the prior executed oath or declaration as filed. No new matter has been added to the revised application.

3. [ ] Small entity status is hereby claimed.

4. [X] The filing fee is calculated below [X] and in accordance with the enclosed preliminary amendment:

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CLAIMS					
	NO. OF CLAIMS		EXTRA CLAIMS	RATE	FEE
Basic Application Fee					$710.00 (101)
Total Claims	84	MINUS 20 =	64	× $18.00 (103) =	1152
Independent Claims	6	MINUS 3 =	3	× $80.00 (102) =	240
If multiple dependent claims are presented, add $270.00 (104)					270
Total Application Fee					2372
If small entity status is claimed, subtract 50% of Total Application Fee					
Add Assignment Recording Fee of $_ if Assignment document is enclosed					
TOTAL APPLICATION FEE DUE					2372.00

5. [ ] Charge $ _____ to Deposit Account No. 02-4800 for the fee due.

6. [X] A check in the amount of $ 2,372.00 is enclosed for the fee due.

7. [X] The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

8. [X] Cancel in this application original claims 1-90 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

9. [ ] New drawings are enclosed.

10. [ ] Priority of Application No. _ filed on _ in _ (country) is claimed under 35 U.S.C. § 119.

    [ ] The certified copy of the priority application

        [ ] is enclosed.

        [ ] was filed on _ in prior Application No. _, filed on _, and acknowledged by the Examiner on _ in Paper No. _.

        [ ] has not yet been filed.

11. [X] Please amend the specification by inserting before the first line the sentence:

21839

[X] --This application is a [ ] continuation [X] divisional of Application No. 08/996,422 , filed on December 22, 1997 .--.

[ ] --This application is a [ ] continuation [ ] divisional of U.S. Application No. _, filed on _, which was a national stage filing under 35 U.S.C. § 371 of International Application No. _ filed on _, which International Application [ ] was [ ] was not published by the International Bureau in English on _.--.

[ ] --This application is a [ ] continuation [ ] divisional of U.S. Application No. _, filed on _, which was a continuation of International Application No. _, filed on _ , which International Application [ ] was [ ] was not published by the International Bureau in English on _.--.

12. [X] A preliminary amendment is enclosed.

13. [X] An Information Disclosure Statement is enclosed.

14. [ ] A General Authorization for Payment of Fees and Petitions for Extensions of Time is enclosed.

15. [X] Also enclosed PTO-Form 1449 Information Disclosure Citation; Data Sheet; and an Acknowledgment Postcard .

16. [X] The power of attorney in the prior application is to Gerald F. Swiss, et al. .
    a. [ ] The power appears in the original papers in the prior application.
    b. [ ] Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
    c. [X] Recognize as Associate Attorney Lawrence S. Squires, Reg. No. 24,060 .
    d. [X] Address all future communications to: (May only be completed by applicant, or attorney or agent of record.)

Gerald F. Swiss
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, Virginia 22313-1404

Date: July 26, 2000

By: Gerald F. Swiss
Gerald F. Swiss
Registration No. 30,113

ADDRESS OF SIGNATOR:

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, Virginia 22313-1404
(650)622-2300

[ ] inventor(s)
[ ] assignee of complete interest
[X] attorney or agent of record
[ ] filed under 37 C.F.R. § 1.34(a)

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